Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/541,019	**Applicant(s)** TSUJI ET AL.	
	Examiner Jeffrey T. Palenik	**Art Unit** 1615	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 September 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *6* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: *See Continuation Sheet*. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1-9,14,17 and 22*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Jeffrey T. Palenik/
Examiner, Art Unit 1615

/Robert A. Wax/
Supervisory Patent Examiner, Art Unit 1615

Continuation of 3. NOTE: Applicants' amendments, were they to be entered on the record, would require further consideration and additional searching on the part of the Examiner. At first glance alone, the amendments made to claims 1 and 17 minimally raise new enablement issues under the first paragraph of 35 USC 112. This is further discussed in Item 11, below.

Continuation of 11. does NOT place the application in condition for allowance because: Applicants' amendments, were they to be entered on the record, would require further consideration and additional searching on the part of the Examiner. As discussed above, the amendments made to claims 1 and 17 minimally raise new enablement issues under 35 USC 112.

At the outset, and in response to Applicants' remarks (see pg. 7, second full paragraph) it should be made clear to Applicants' that the amended "peptide transporter 1" is in no way considered to be a part of the instantly claimed composition and that such a recitation would be met with a rejection under 35 USC 101. The invention is interpreted by the Examiner as being directed to a composition comprising the actual compound which is recognized by said transporter and the pH-sensitive polymer with which it is combined.

Concerning the amended transporter of claim 1 and 17, it is noted that Applicants expressly discuss the location within the body of the "peptide transporter 1" or "PEPT1" as being either in the kidneys or the small intestine (see specification pg. 7, lines 19-23). Given that Applicants have narrowed the scope of the target to within the small intestine, it stands to reason that the pH range of the small intestines will not enable the compound to be released. Turning to that which is known in the art concerning pH-sensitive polymers (e.g., Eudragit polymers), the person of ordinary skill in the pharmaceutical arts would immediately recognize the different blends of Eudragit and the release properties thereto. Specifically, it is known that where said polymers are sensitive to pH, different blends react to different pH ranges (see attached diagram from Eudragit website). Applicants readily acknowledge this teaching as evidenced by the 8 attached pages to their Remarks discussing the different blends.

Turning back to the amended claims, the issue of enablement arises because polymers other than methacrylic acid copolymer L or LD (i.e., Eudragit blends L100-55, L100, L12,5 and/or L30 D-55) are claimed as embodying the pH-sensitive polymer. Given the location of PEPT1 it is unclear how other of the claimed polymers (e.g., Eudragit S blends) are capable providing the intended release property. Applicants' amendments are denied entry on this issue alone.

Concerning Applicants' arguments directed to the actual teachings of Timmins, said arguments have been given full consideration, but they are not persuasive.

The crux of Applicants' assertions is that Timmins not only fails to "specifically disclose a pharmaceutical preparation comprising a peptide transporter 1", but also the use of a pH-sensitive polymer present between 5-40 wt% of the entire pharmaceutical preparation.

The fact that the composition does not contain the actual transporter target itself is discussed above.

Concerning the polymers which are expressly taught by the reference, Applicants' fully acknowledge that polymers such as Eudragit "L", "S" and "L100-55" are taught. Applicants' then further assert that the reference does not disclose, teach or suggest that the pH-sensitive polymer is present in an amount of 5-40 wt% of the entire composition and that Timmins does not recognize the importance of the pH-sensitive polymer.

The Examiner respectfully disagrees with both of these points. Timmins, as well as the ordinarily skilled artisan, clearly recognize the importance of the pH-sensitive polymer. At the very least, Timmins' use of the tradenames and blend designations for the different Eudragit compounds demonstrates an understanding that not all Eudragit blends function the same. Even were that assumption to be made, it would be well within the purview of the ordinarily skilled artisan to research and ascertain the differences and capabilities of each blend, again as evidenced by Applicants' attachments to the response. Concerning the amount of polymer admixed with the recognized compound, Timmins clearly discloses that the amount of polymer which may be used, ranges as broadly as from 5-95 wt% and preferably from 7-85 wt% of the composition (col. 9, lines 59-67 and col. 10, lines 9-16). At the very least, the instantly claimed range is both taught and suggested by the preferred range. Applicants have provided no showing of evidence to suggest otherwise.

Lastly, Applicants' discussion of Example 2 and Figure 2 (Remarks, pg. 10) pitting the "L 100-55" blend against the "RS" blend of Eudragit is unpersuasive. At the very least, the "RS" blend is not excluded from the instantly claimed composition as said composition is recited as "comprising" components (a) and (b). See MPEP §2111.03. Furthermore, the composition, as instantly claimed, is not commensurate in scope with the cited Examples of the specification (e.g., Examples 2 and 4).

For these reasons, had Applicants' amendments been entered on the record, the rejections currently of record would have been maintained.